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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 08/479,995	Applicant(s) Pengolizi et al.
Examiner Ardin Manschel	Group Art Unit 1809

Responsive to communication(s) filed on 7-25-97

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 283-362, 364-380, 382-398, 400-404, and 406-460 is/are pending in the application.

~~The above, Claim(s) 1-282, 363, 381, 399, and 405 have been canceled~~ ~~is/are withdrawn from consideration.~~

Claim(s) 283-298, 298-306, 304, 307, 309-321, 323-333, 335-340, 347, 350, 353, 353-362, 364-367, 374-380, is/are allowed.

Claim(s) 382-385, 392-398, 400-403, 406-409, 411, 413, 414, 416, 418, 419, 422-425, 430-433, 436-460 is/are rejected.

Claim(s) 297, 302, 303, 305, 306, 308, 322, 334, 341-346, 348, 349, 351, 352, 354-357, 368-373, is/are objected to.

Claim(s) 386-391, 404, 410, 412, 415, 417, 420, 421, 426-431, 434, and 435 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, ~~Paper(s)~~ 4 sheets

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Applicants' arguments and IDS, filed 7/25/97, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Consideration of the foreign patent application prosecution reveals that they are incomplete. The 3 U.S. Patents that were listed are of interest and may be significant in future prosecution but do not negate the bases for the art rejections given below.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

The NEW MATTER rejection directed to the phrase in claim 300, lines 3-4, the phrase being "an analog-containing polymer" is reiterated and maintained as given in the previous office action, mailed 3/11/97. This phrase adds NEW MATTER in that written basis for generic polymers containing analogs has not

been found. Consideration of the support cited by applicants reveals that polynucleotides of various types are listed but not more generic polymers. Another interpretation is that NEW MATTER is added via unclarity of the metes and bounds of such polymers. Claims 315, 321, and 328 also contain this NEW MATTER and claims 317 and 318 via dependence from the above claims. Applicants argue that several polymer types are cited such as polysaccharides and proteins as well as nucleic acid polymers. This is non-persuasive since consideration of claims 315 etc. reveals that they are firstly limited to oligo- or polynucleotides. Therefore, protein polymers, for example, are not related to the analog limitations of claims 315 etc. It is noted that attachments to oligo- or polynucleotides have written support as filed but not the generic concept of analogs as given in claims 315 etc. Amendment to such attachments to replace the analog amendments to these claims is suggested.

Claims 315, 321, and 328 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the above objections to the specification.

Claims 347, 364, 365, 376, 377, 382, 383, 394, 395, 400, 401, 406, 407, 439, 440, 442, 444, 446, 448, 450, 452, 454, 456, and 460 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The last line of claim 347 is confusing in context in citing

a binding step in a selection group of a composition claim.

Claims 364 and 365 are vague and indefinite because complex formation cited therein conflicts with claims from which they depend. For example, claim 364 depends from claim 444 wherein claim 444 cites the providing of a complex, cited in line 3 therein, between a molecular bridging entity and the one or more signalling entities and a separate step wherein said complex forms a further complex with the analyte. This conflicts with claim 364 wherein the analyte first complexes with the bridging entity and thereafter a second complex is formed by the addition of the signalling entity. Similarly, claims 446 and 448 conflict with claim 364. Similarly, claim 365 seems to repeat the complex ordering in the same manner as claims 444, 446, or 448. What added limitation(s) are therefore meant by the wording of claim 365 over claims 444, 446, or 448? The same set of conflicts exist between claims 382 and 383 versus claims 450, 452, and 454; as well as claims 400 and 401 versus claim 456; as well as claims 406 and 407 versus claim 460

Claims 439 and 440 are vague and indefinite due to depending from a canceled claim.

Claim 442 is vague and indefinite because claim 442 cites the formation of a complex that is apparently already formed in claims 285, 290, and 294. What is meant by this repetitive citation of complex formation? Clarification is requested.

Claims 376, 377, 394, and 395 are vague and indefinite because certain claim dependencies result in two complexes being

formed. These claims cite fixing or immobilizing before forming the complex, but it is unclear which complex is meant.

Claims 312, 318, and 330 are rejected, as discussed below, under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claims 312, 318, and 330 cite all options for modifications and thus fail to further limit the claims from which they depend.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 283-296, 298-301, 304, 307, 309-321, 323-333, 335-340, 347, 350, 353, 358-362, 364, 366, 367, 374-376, 378-380, 382, 384, 385, 392-394, 396-398, 400, 402, 403, 406, 408, 409, 411, 413, 414, 416, 418, 419, 422-425, 432, 433, 436-438, 441-443, 445, 447, 449-455, and 457-459 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Dunn et al.

Dunn et al. reads on the above listed claims due to its disclosure of an immobilized target analyte wherein a bridging entity is hybridized thereto followed by washing and then the hybridization of a nick translated radiolabelled signalling entity that is made up of a heterogeneous mixture of radiolabelled fragments produced as a result of the nick

translation process. This nick translation process also results in a ratio of signalling entities as being clearly greater than 1 as compared to bridging entities, but is unclear how much greater than 1. This rejection is maintained and reiterated as given in the previous office action, mailed 3/11/97. Applicants firstly argue that the Dunn et al. disclosure utilizes sandwich hybridization wherein the two reagent entities hybridize to two separate portions of the target. This is entirely contrary to the Dunn et al. reagents wherein there is an entity that hybridizes to the target RNA said entity having a tail. The nick translated signal entities hybridize to said tail and not to the target RNA thus making this argument of applicants moot as directed to a mischaracterization of the disclosure of Dunn et al. The second argument is that the signalling entities be substantially incapable of hybridizing to the molecularly recognizable portion on the analyte. This argument is also non-persuasive because the Dunn et al. disclosure labels the target only via a sandwich formed wherein one reagent hybridizes to the target thus making it an incapability for the signalling entity to hybridize thereto thus inherently meeting the instant claim limitations. Another element of support for the substantial incapability of the signalling entity to hybridize to the target recognizable portion is that these are distinct sequences in that one is Adenovirus type 2 sequence and the other is SV40 sequence. These are well known to be different and distinct sequences thus being substantially incapable of hybridization as required for

the instant claims and also supporting the rejection. Applicants then argue a lack of one continuous chain comprising the complementary sequences for the molecular bridging sequence entity and the sequence for the signalling entity. This is confusing and non-persuasive since this is exactly what is both disclosed in Dunn et al. and in the instant claims. Again mischaracterization of the instant invention and/or the disclosure of Dunn et al. is not persuasive to overcome the rejection. Applicants then summarize several references that refer to sandwich hybridization and credit various authors for suggesting or disclosing them. It is acknowledged that sandwich hybridization is a phrase that may be applied to both the Ranki et al. type of assay as well as the Dunn et al. type of assay but that the location of the entity that is the target is different but that there are similarities in the sandwiches that are formed. Since the Dunn et al. disclosure is directed to mapping RNA sequences, this is deemed to be the target. This target is located the same both in the Dunn et al. disclosure as well as in the practice of the instant invention and thus supports this rejection. It is noted that the target in the Ranki et al. type of sandwich hybridization is in the middle of the sandwich and different from that of Dunn et al. as well as the instant invention. Applicants then argue that Dunn et al. did not teach the detection of an unknown analyte. This is non-persuasive because the analyte must be known regarding sequence in both the Dunn et al. disclosure as well as the instant invention in order

to direct the synthesis of the target recognition portion of the bridging entity. This was required for the Dunn et al. procedure as well as for the instant invention. The bridging entity, in other words, must be designed from knowledge of the target sequence.

The rejection under 35 U.S.C. § 103(a) is withdrawn in view of the commercial success supported by the significant commercial interest including the three U.S. Patents cited in arguments of applicants.

Claims 297, 302, 303, 305, 306, 308, 322, 334, 341-346, 348, 349, 351, 352, 354-357, 368-373, 386-391, 404, 410, 412, 415, 417, 420, 421, 426-431, 434, and 435 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Enclosed is an executed PTO Form 1449 with several references lined through to avoid duplication of citation on 1449s or 892s already in the file.

No claim is allowed.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

October 27, 1997

*Ardin H. Marschel*

ARDIN H. MARSCHEL  
PRIMARY EXAMINER  
GROUP 1800